UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,496	02/12/2004	Christopher Charles Andrews	327723	5259

42074 7590 07/09/2008

FAEGRE & BENSON, LLP
32469
2200 WELLS FARGO CENTER
90 SOUTH SEVENTH STREET
MINNEAPOLIS, MN 55402-3901

EXAMINER	
LANG, AMY T	
ART UNIT	PAPER NUMBER
3731	

NOTIFICATION DATE	DELIVERY MODE
07/09/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

e-OfficeActionBSC@faegre.com

Office Action Summary	Application No.	Applicant(s)	
	10/777,496	ANDREWS ET AL.	
	Examiner	Art Unit	
	AMY T. LANG	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-11* is/are pending in the application.

4a) Of the above claim(s) *10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-9, and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Claims 1-3, 5-11 are pending. Claim 10 has been withdrawn frm consideration as directed to non-elected invention.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

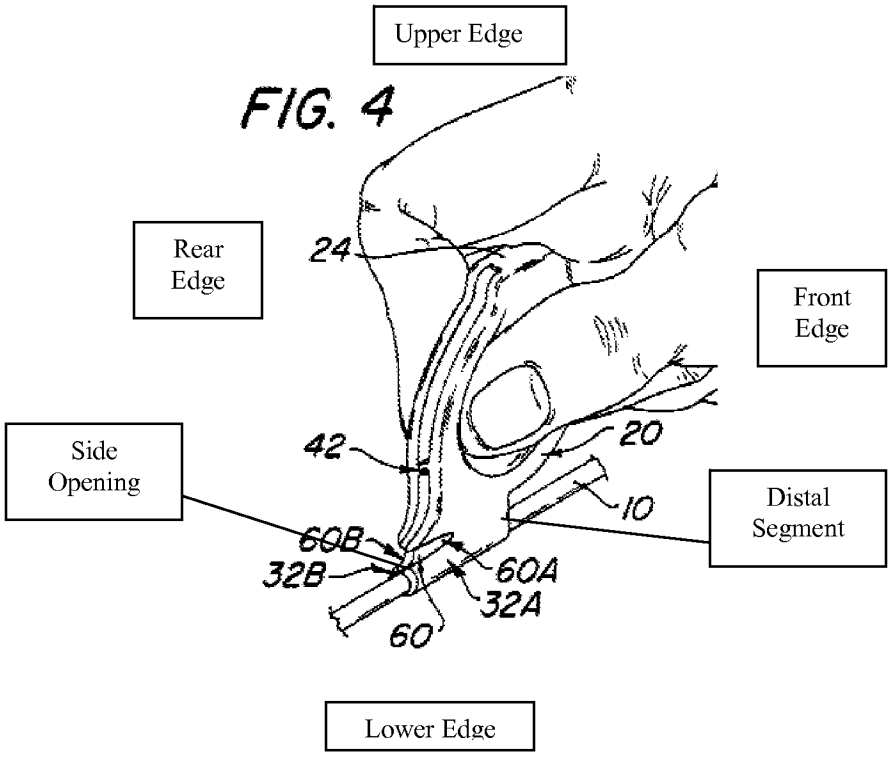
2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. **Claims 1-3 and 9** are rejected under 35 U.S.C. 103(a) as being unpatentable over Brenner (US 6,497,681 B1).

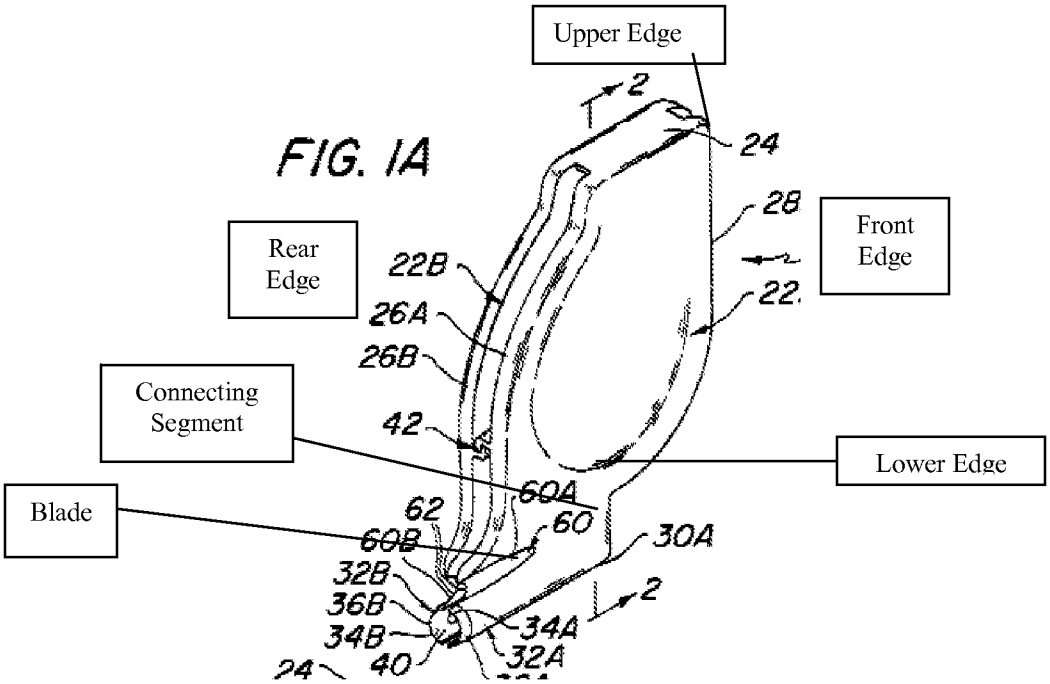
With regard to **claims 1 and 9**, Brenner discloses a device for removing a guide catheter from a linear lead (see entire document). The device comprises a body (20) having a front, rear, upper, and lower edge. As shown in Figure 4 and below, Brenner discloses a distal lead management segment having an outer surface and comprising a side opening member, the rear opening (column 5, line 66 through column 6, line 6). The lumen through the side opening

overlaps the instantly claimed central opening since it is sized to engage the linear lead (column 6, lines 3-5). As shown in Figure 1A and 16, the side opening is configured to deform, change shape from an opened configuration to a closed configuration, to snap and secure the linear object in place. It is the examiner position that closing the side opening around the linear lead to secure the linear lead comprises snapping the side opening around the linear lead. Additionally, rib members (42A, 42B) are snapped into place to secure the linear lead in the central opening (column 6, lines 38-43).



As shown above, the distal segment is positioned adjacent the lower edge of the body and extends generally from the front edge toward the rear edge. Since the device of Brenner only secures the linear lead, it is adapted to allow the guide catheter to pass about a surface of the distal segment.

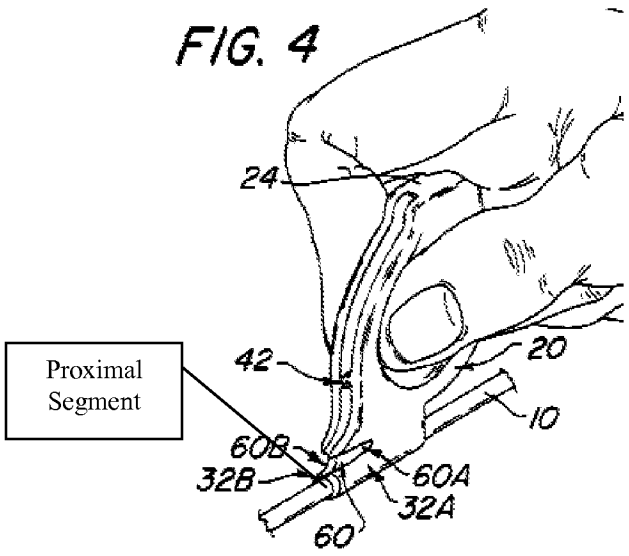
Brenner further discloses a blade (60) mounted between the lower edge and the distal segment and supported by a connecting segment between the lower edge and the distal segment (column 7, line 61 through column 8, line 10). The blade comprises a first and second cutting portion (60A and 60B), wherein each is angled from the front edge toward the rear edge (Figure 11). A notch is formed between the two blade tips (Figure 1A).



Although Brenner does not specifically disclose the connecting segment as a web, it is the examiner's position that it would have been obvious at the time of the invention to one ordinary skill in the art for the connecting segment to comprise several cavities. This would advantageously reduce the weight of the device which allows for easier manipulation. Therefore, the connecting segment of Brenner comprising several cavities would clearly overlap the instantly claimed web.

With regard to **claim 2**, as shown in Figure 1A the notch is positioned close to the distal segment and therefore clearly overlaps the instantly claimed proximate.

With regard to **claim 3**, it is the examiner's position that the front opening of the distal segment also overlaps the instantly claimed side opening member. Therefore, the rear opening of the distal segment overlaps the instantly claimed arcuate side opening forming a central opening and therefore overlaps the instantly claimed proximal segment. As shown below, the linear lead is inserted through the proximal segment central opening.



4. **Claims 1-3, 5-9, and 11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gardeski et al. (US 2003/0181935 A1).

With regard to **claims 1 and 9**, Gardeski et al. (hereinafter Gardeski) discloses a device for removing a guide catheter from a linear lead (see entire document). The device comprises a body (51) having a front, rear, upper, and lower edge. As shown in Figure 4 and below, Brenner discloses a distal lead management segment having an outer surface and comprising a side

opening member, the rear or front opening ([0050]). The lumen through the side opening (72) overlaps the instantly claimed central opening since it is sized to engage the linear lead. Since the distal segment is located near the lower edge, it is adjacent the lower edge. Additionally, the device of Gardeski only secures the linear lead so that it is adapted to allow the guide catheter to pass about an outer surface of the distal segment.

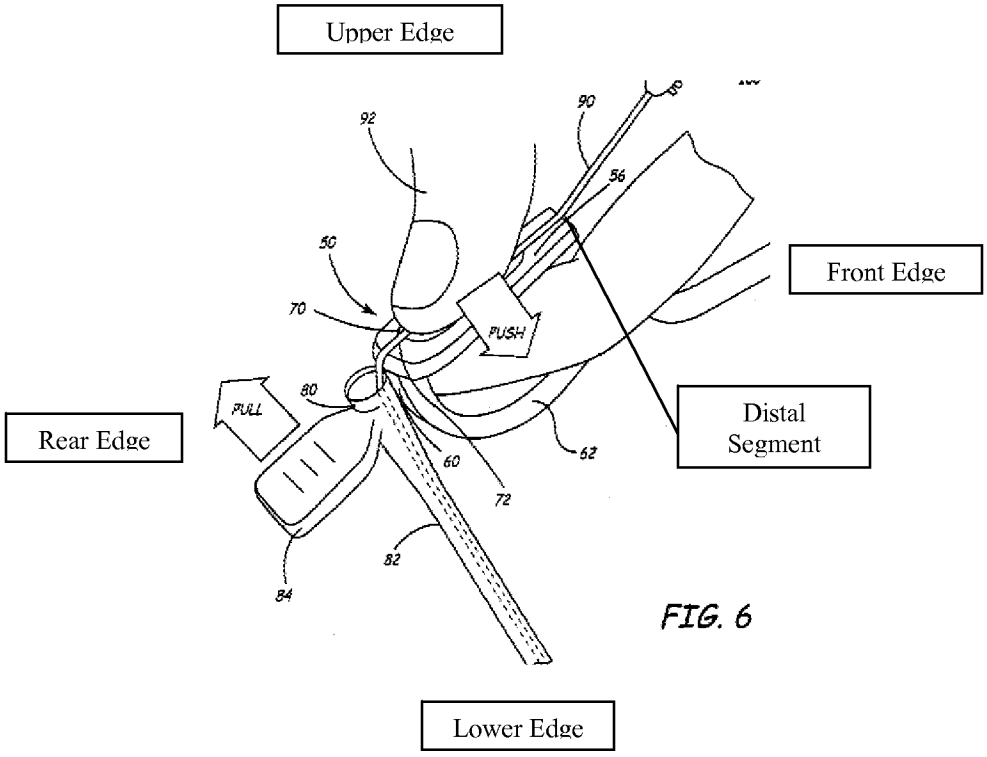


FIG. 6

A blade (60) is mounted between the lower edge and the distal segment and supported by a connecting segment located between the lower edge and the distal segment (column 7, line 61 through column 8, line 10). The blade is further disclosed as having a sawtooth configuration,

which clearly overlaps the first and second cutting portions ([0045]). Further, a notch would be present between each cutting portion.

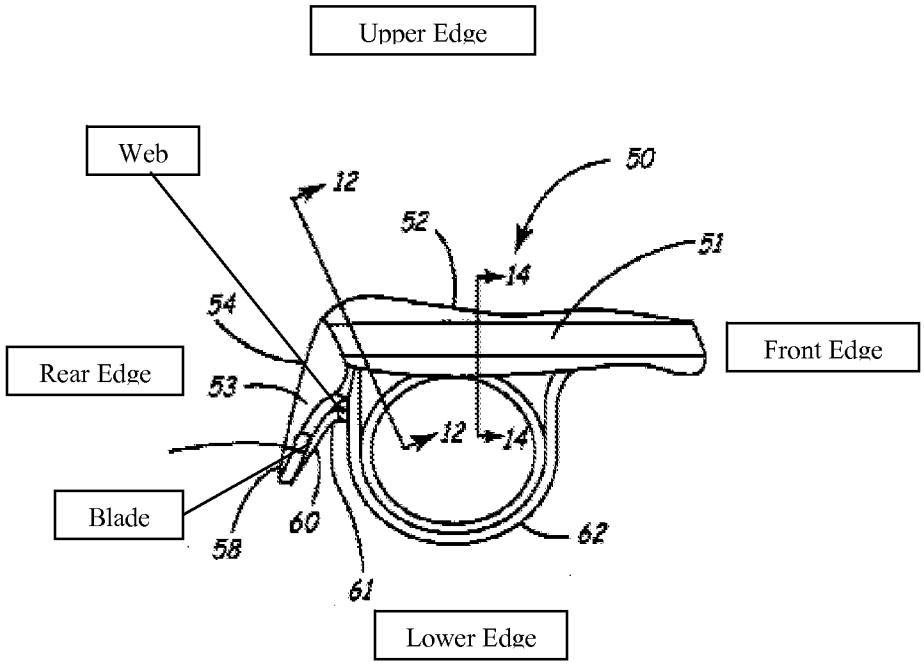


FIG. 3

Brenner does not specifically disclose (i) the connecting segment as a web or (ii) the side opening member configured to deform and such that the linear object can be snapped into the central opening.

With regard to (i) above, it is the examiner's position that it would have been obvious at the time of the invention to one ordinary skill in the art for the connecting segment to comprise several cavities. This would advantageously reduce the weight of the device which allows for easier manipulation. Therefore, the connecting segment of Gardeski comprising several cavities would clearly overlap the instantly claimed web.

With regard to (ii) above, Gardeski teaches that the central opening (72) is sufficiently deep to receive the entire linear lead body ([0051]). Gardeski further disclose the central opening and side opening member comprised of a low durometer polymer ([0059]). Since a low durometer polymer is capable of deforming when contacted, it would have been obvious at the time of the invention for the central opening and side opening member of Gardeski to be sized accordingly so that the linear lead is snapped into the central opening causing the polymer of the side opening member to deform.

With regard to **claim 2**, since the cutting blade (60) is positioned close to the distal segment and comprises the notch, it is the examiner's position that the notch is proximate the distal segment (Figure 3).

With regard to **claim 3**, Gardeski also discloses an arcuate side opening forming a central opening and therefore overlaps the instantly claimed proximal segment.

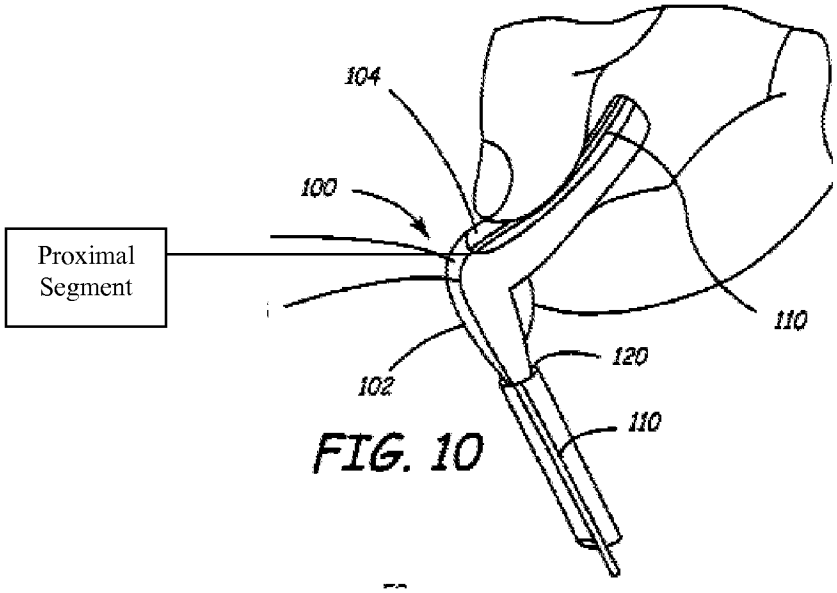


FIG. 10

With regard to **claim 5**, Gardeski discloses a device for removing a guide catheter from a linear lead comprising a proximal and a distal segment. Gardeski further teaches wherein

channel (72), which runs through the proximal and distal segments, varies in size and shape along the length of the channel. Although Gardeski does not specifically disclose wherein the distal segment has a forward smaller diameter and a rearward larger diameter, since this limitation is within the scope of Gardeski, it would have been obvious to one of ordinary skill at the time of the invention for the distal segment of Gardeski to have a forward smaller diameter and a rearward larger diameter.

With regard to **claims 6 and 11**, Gardeski discloses laterally opposing wings, one of which is shown below.

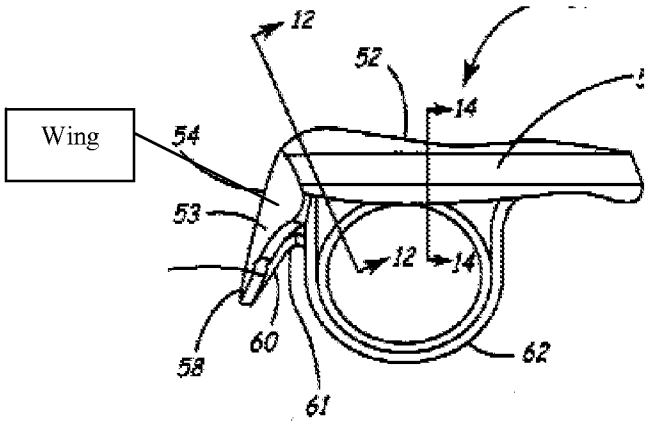


FIG. 3

With regard to **claim 7**, it is also the examiner's position that when the distal segment comprises a forward smaller diameter and a rearward larger diameter, a transition point would be created between these two segments. As shown in Figure 3, the wings would be close to the transition point and therefore adjacent.

With regard to **claim 8**, Gardeski discloses a nose (53) extending from the distal segment and adapted to be inserted within the guide catheter (Figure 3; [0047]).

Response to Arguments

5. Applicant's arguments with respect to claims 1-3, 5-9, and 11 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY T. LANG whose telephone number is (571)272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

07/02/2008
/Amy T Lang/
Examiner, Art Unit 3731

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731